

Case Number:	CM14-0029329		
Date Assigned:	07/25/2014	Date of Injury:	10/22/2009
Decision Date:	12/03/2014	UR Denial Date:	02/18/2014
Priority:	Standard	Application Received:	03/07/2014

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The expert reviewer is Board Certified in Neurology, has a subspecialty in Neuromuscular Medicine, and is licensed to practice in New Jersey. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

The patient is a 57-year-old man who sustained a work-related injury on October 22, 2009. Sequentially, he developed with chronic back pain, right shoulder and right knee pain. The patient was diagnosed with lumbar discopathy, right shoulder impingement syndrome, and bilateral plantar fasciitis. The patient underwent Right Knee Arthroscopic Surgery and Bilateral Inguinal Hernia Surgery. According to a progress report dated on April 22, 2015, the patient was complaining of significant back pain, right shoulder right knee and bilateral feet pain. The patient was also complaining of headaches. The patient physical examination demonstrated right shoulder tenderness to with positive impingement sign, lumbar tenderness with reduced range of motion, right knee tenderness to positive McMurray sign. There is no documentation of more recent evaluation. The provider request authorization to continue the use of Cyclobenzaprine, Tramadol, and Sintralayne.

IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

Cyclobenzaprine Hydrochloride tablets 7.5mg #120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants (For Pain).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants Page(s): 63.

Decision rationale: According to MTUS guidelines, Cyclobenzaprine a non-sedating muscle relaxants is recommended with caution as a second line option for short term treatment of acute exacerbations in patients with chronic spasm and pain. Efficacy appears to diminish over time and prolonged use may cause dependence. The guidelines do not recommend being used form more than 2-3 weeks. The patient in this case does not have clear significant functional improvement with prior use of muscle relaxants. There is no indication of recent evidence of spasm. Cyclobenzaprine was previously used without clear documentation of efficacy. Therefore, the request for Cyclobenzaprine Hydrochloride Tablets 7.5 Mg Qty: 30 is not medically necessary.

Tramadol Hydrochloride Extended-Release Capsules 150 MG #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol Page(s): 113.

Decision rationale: According to MTUS guidelines, Ultram (Tramadol) is a synthetic opioid indicated for the pain management but not recommended as a first line oral analgesic. In addition and according to MTUS guidelines, ongoing use of opioids should follow specific rules :(a) Prescriptions from a single practitioner taken as directed, and all prescriptions from a single pharmacy. (b) The lowest possible dose should be prescribed to improve pain and function. (c) Office: Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or non-adherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework. In this case, there is no clear evidence of objective and recent functional and pain improvement from previous use of narcotics. There is no recent objective documentation of pain severity level to justify the use of narcotics in this patient. There is no clear documentation of the efficacy/safety of previous use of opioids. There is no recent evidence of objective monitoring of compliance of the patient with her medications. Therefore, the prescription of Tramadol Hydrochloride ER 150# 90 is not medically necessary.

Sintralyn PM #30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Treatment in Workers Compensation (TWC), Pain Procedure Summary

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) < <http://worklossdatainstitute.verioiponly.com/odgtwc/pain.htm#Medicalfood> >

Decision rationale: According to ODG guidelines, medical food. < Recommended as indicated below. Definition: Defined in section 5(b) of the Orphan Drug Act (21 U.s.c.360ee (b) (3)) as "a food which is formulated to be consumed or administered entirely under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." To be considered the product must, at a minimum, meet the following criteria: (1) the product must be a food for oral or tube feeding; (2) the product must be labeled for dietary management of a specific medical disorder, disease, or condition for which there are distinctive nutritional requirements; (3) the product must be used under medical supervision. See Food labeling; Reference Daily Intakes and Daily Reference Values; Mandatory Status of Nutrition Labeling and Nutrition Content Revision proposed rule (56 FR 60366 at 60377, November 27, 1991). Medical foods are exempted from the labeling requirements for health claims and nutrient content claims under the Nutrition Labeling and Education Act of 1990. Medical foods do not have to be registered with the FDA. There are no controlled studies supporting the safety and efficacy for the use of Sintralyn for the treatment of pain. Furthermore, there no documentation that the patient suffered from a nutrition deficit that requires the use of Sintralyn. Based on the above, the prescription of Sintralyn is not medically necessary.

Medrox Pain Ointment 120 Gm X 2: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111.

Decision rationale: Medrox ointment is formed by the combination of Methyl Salicylate, Capsaicin, and Menthol. According to MTUS, in Chronic Pain Medical Treatment, guidelines section Topical Analgesics (page 111); topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Many agents are combined to other pain medications for pain control. That is limited research to support the use of many of these agents. Furthermore, according to MTUS guidelines, any compounded product that contains at least one drug or drug class that is not recommended is not recommended. Medrox patch contains Capsaicin a topical analgesic not recommended by MTUS. Furthermore, there is no documentation of failure or intolerance of first line oral medications for the treatment of pain. Based on the above Medrox ointment is not medically necessary.